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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,540	07/10/2001	Barry S. Goldman	38-10(15849)B	6847

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MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,540	Applicant(s) GOLDMAN ET AL.	
	Examiner Carolyn L Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,11-19,27-31 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *14-16,27,28,30,31 and 34-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,11-13,17-19,29,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,8,11-19,27-31 and 34-39* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Sequence match listings (6 pages).

DETAILED ACTION

Applicants' election with traverse of Group I (claims 1, 8-13, 17-19, and 29), the cancellation of claims 9 and 10, the amendment of claims 1, 8, 11, 17, and 29, and the addition of new claims 38 and 39 in Paper No. 5, filed 11/6/02, are acknowledged. Applicants appear to have elected Group I but made a typographical error in the list of claims to be examined. Examiner maintains that Group I consists of claims 1, 8-13, 17-19, and 29 as stated in the Restriction (Paper No. 4), mailed 9/6/02. The applicants' sequence election of SEQ ID NO: 4639 within the restriction of Group I is also acknowledged. The cancellation of claims 2-7, 20-26, and 32-33 and the amendments of claims 12, 14, 15, 17, and 36 in Paper No. 3, filed 11/9/01, are acknowledged. Claims 14-16, 27-28, 30-31, and 34-37 are withdrawn from consideration as being drawn to non-elected Groups.

Applicants' election with traverse of Election/Restriction Requirement in Paper No. 4, mailed 9/6/02, is acknowledged. The traversal is on the grounds that there is insufficient support for limiting the number of nucleic acid sequences to one sequence and separating the claims into 5 inventions.

The traversal to limiting the number of nucleic acid sequences to one was found unpersuasive because, due to the number of these requests made, it is practically impossible to accommodate all requests. The overwhelming number of sequences poses undue search burden when more than one nucleic acid sequence is elected, thus making the previous waiver to a search of more than one sequence, effectively impossible to reasonably implement.

The applicants' traversal referring to an undue division of the five separate inventions into one was found unpersuasive because of the following reasons (reiterated from the restriction paper):

The inventions are distinct, each from the other because of the following reasons: The inventions of Groups [I, IV (nucleic acid specie), and V]; [II and IV (polypeptide specie)]; [III]; and [IV] are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, IV (nucleic acid specie), and V, the critical feature is a polynucleotide. For Groups II and IV (polypeptide specie), the critical feature is a polypeptide. For Group III, the critical feature is a computer readable medium. For Group IV, the critical feature is collection of either polynucleotides or polypeptides. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the four Groupings: [I, IV (nucleic acid specie), and V]; [II and IV (polypeptide specie)]; [III]; and [IV] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, IV (nucleic acid specie), and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the polynucleotide of Group I may be utilized in distinct usages as needed in Group IV for a collection of polynucleotides, in a method for determining gene expression as in Group V, or alternatively, in antisense therapy. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups II and IV (polypeptide specie) are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the polypeptide of Group II may be utilized in distinct usages as needed in Group IV for a collection of peptide molecules, or alternatively, in cell growth inhibition studies and preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

The requirements are still deemed proper and are therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed

to *Myxococcus xanthus* genome sequences and uses thereof whereas in contrast the elected claims include a nucleic acid, primers for amplifying the nucleic acid, and transformed cells and organisms containing the nucleic acid.

Claims herein under examination are claims 1 (amended), 8 (amended), 11 (amended), 12 (amended), 13, 17 (twice amended), 18, 19, 29 (amended), 38 (new), and 39 (new).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 39, lines 4 and 14, and elsewhere. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claims Rejected Under U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1, 8, 11-13, 17-19, 29, 38, and 39 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence. For a sequence putatively assigned a biological function (page 54, line 3), even if correct, does not appear to be defined as to what use it is to be applied to. The significance of the sequence is undefined, further rendering it indiscernible how someone of skill in the art would use such an entity.

Due to the large quantity of experimentation necessary to determine activity or property of the disclosed nucleic acid such that it can be determined how to use the claimed sequence, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, and the breadth of the claims which fail to recite particular biological activities, the specification fails to teach the skilled artisan how to make and use the claimed invention.

LACK OF WRITTEN DESCRIPTION

Claims 1, 8, 11-13, 17-19, 29, 38, and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 4639 which corresponds to DNA encoding a protein of SEQ ID NO: 11926. SEQ ID NOs: 4639 and 11926 and their full length complements meet the written description provisions of 35 USC 112, first paragraph. However, claims 1, 8, 11-13, 17-19, 29, 38, and 39 are directed to encompass gene sequences, sequences that hybridize to SEQ ID NO: 4639, sequences that have a recited degree of identity (similarity, homology) and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Due to the open claim language wording of "comprising" and "comprises" as cited in claims 1 (line 2), 11 (line 2), 17 (line 2), 29 (line 2); "having" of claim 17 (line 1); and "has" as cited in claims 38 (line 2) and 39 (line 2); these claims and any dependent claims therefrom encompass gene sequences that do not meet the written description provision of 35 USC 112, first paragraph. Please note the "70 percent identity" and "90 percent identity" as recited in claims 38 (line 2) and 39 (line 2), respectively, could also contain sequences including the entire sequence of SEQ ID NO: 4639 plus up to 30% and 10%, respectively, of additional sequence on either end of SEQ ID NO: 4639 which also fail to meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 12, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai

Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 4639 and nucleic acids specifically encoding 11926 but not the full breadth of claims 1, 8, 11-13, 17-19, 29, 38, and 39 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 11-13, 17-19, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 11 recites the phrase "comprising *the* sequence" which is vague and indefinite. It is unclear whether the sequence is referring to the entire sequence or just a fragment of the sequence. Claims 1, 8, 12-13, and 17-19 are also rejected due to their dependency from claim 11.

Claim 12 recites the phrase "is complementary to" which is vague and indefinite. The claim does not adequately define the phrase which could mean the complementarity is 100% similarity and of the same length of the claimed sequence, or 90% similarity and only a fragment of the claimed sequence, or any other scenario. Appropriate definition of the degree of complementarity to the claimed sequence is required. Claim 13 is also rejected due to its dependency from claim 12.

Claim 12 recites the words "sufficient" which is vague and indefinite. It is unclear what is meant by "sufficient" as it is relative terminology. Clarification of the metes and bounds of claim 12 via clearer claim wording is required. Claim 13 is also rejected due to its dependency from claim 12.

Claim 29 recites the phrase "homologous or complementary" which is vague and indefinite. The claim does not adequately define the degree of homology or complementarity of the primer. Appropriate definition of the degree of homology or complementarity is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11, 17, 19, 29, 38, and 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Darwin et al. (1993). As "*the* sequence" (of claim 11) was undefined regarding the entire sequence or a fragment of the sequence, Darwin et al. disclosed a gene and its translated sequence (Fig. 2B, amino acid positions 262-265) which contains an identical matching polynucleotide sequence (nucleotide positions 1086-1096, sequence match listing) to a fragment of SEQ ID NO: 4639 (nucleotide positions 910-920) which encodes SEQ ID NO: 11926 as stated in claims 1, 11, 38, and 39. Darwin et al. disclosed the structural gene, nrfA, which encodes a nitrate pathway protein (abstract, lines 1-3) as stated in claims 11, 38, and 39. Darwin et al. disclosed an nrfA promoter (abstract, line 25, Fig. 1B, and Fig. 2A) as stated in claim 8. Darwin et al. disclosed a transformed bacterial organism containing the promoter which caused the production of mRNA (page 1256, col. 2, lines 17-19; page 1257, col. 2, lines 11-13; and page 1261, col. 1, lines 6-9) as stated in claims 17 and 19. Darwin et al. disclosed nrfA probes (page 1260, col. 1, lines 23-25 and col. 2, lines 1-6; and page 1264, col. 2, lines 8-14) as stated in claim 29. Thus, Darwin et al. teach all of the limitations in claims 1, 8, 11, 17, 19, 29, 38, and 39.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 12, 2002

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER